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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,825	10/29/2003	James C. Kennedy	67286-277	2824
22428	7590	06/02/2006	EXAMINER	
FOLEY AND LARDNER LLP			SHARAREH, SHAHNAH J	
SUITE 500			ART UNIT	PAPER NUMBER
3000 K STREET NW				1617
WASHINGTON, DC 20007			DATE MAILED: 06/02/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/605,825	KENNEDY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shahnam Sharareh	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

(55)

1) Responsive to communication(s) filed on 15 November 2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 15-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/27/2005.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicant's Amendment filed on November 15, 2005 has been entered. Claims 15-25 are pending.

### ***Response to Arguments***

Applicant's arguments with respect to the pending claims have been fully considered but are not persuasive for the reasons described below.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-19, 21-25 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating malignant skin lesions with 5-aminolevulinic acid (5-ALA), does not reasonably provide enablement for the entire scope of the claims directed methods of treating any malignant skin lesions including for example Sacromas secondary to an HIV infection with any agent which is not in itself a photosenitizer but which induces accumulation of protoporphyrin IX in a cellular target. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons discussed in the last Office Action filed on August 11, 2005.

Applicant relying on three cited references, McGilvery et al, DeMatties et al, and Srivastava (filed on November 15, 2005) has argued that one of ordinary skill in the art would have been able to determine the scope of the compounds to be employed in the

instant pending claims. (see Remarks at page 4). Applicant further appears to argue that one of ordinary skill in the art would have understood, relying on the teachings of McGilvery, that such compounds are limited to those commonly known in the heme biosynthetic pathway. (see Remarks at page 4, the last 4 lines).

In response Examiner states that such line of arguments is an attempt to constructively reading limitations from the specification and the teachings of prior art into the pending claims. However, Examiner maintains that reading a claim in light of the specification and the state of art, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from "reading limitations into a claim, to thereby narrow the scope of the claim by implicitly adding limitations which have no express basis in the claim."

Here Applicant advocates the impermissible importation of subject matter from the specification and prior art into the claim to narrow the scope of the claims for the purposes of satisfying the 112, 1<sup>st</sup> paragraph. There is no clear definition in the specification that limits the phrase "agents which is not a photosensitizer but induces the syntheses of protoporphyrin IX in vivo," to only such compounds that are involved in the biosynthetic pathway of heme as shown in McGilvery. Accordingly, for such reasons the arguments are not persuasive.

#### ***Double Patenting***

Claims 15-25 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-2 of US Patent 5,211,938; claims 1-7 or US Patent 5,079,262; claims for the reasons of record.

Claims 15-25 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/663,992; claims 1-20 of copending application, 10605,826; claims 1-19 of copending application 09/928,505 and the claims 1-15 of copending application 09/816,329 for the reasons of record.

Applicant's intention to file a Terminal disclaimer to overcome such rejection is noted in the Remarks filed on November 15, 2005.

***Allowable Subject Matter***

Claim 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> paragraph and under Double Patenting Statute, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

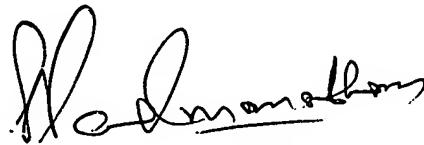
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER